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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			<b>Complete If Known</b> Application Number: 10/823,973 Filing Date: April 14, 2004 First Named Inventor: Gibbons et al Group Art Unit: Examiner Name: Attorney Docket Number: AM-101323USA				
Sheet	1	of	6	U.S. PATENT DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2a</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
BF	A	US-3,929,992	12-30-1975	Sehgal et al			
	B	US-3,993,749	11-23-1976	Sehgal et al			
	C	US-4,401,653	08-30-1983	Chee P.Eng			
	D	US-5,078,999	01-07-1992	Warner et al			
	E	US-4,885,171	12-05-1989	Surendra et al			
	F	US-5,080,899	01-14-1992	Sturm et al			
	G	US-5,100,899	03-31-1992	Sir R. Calne			
	H	US-5,362,718	11-08-1994	Skotnicki et al			
	I	US-5,321,009	06-14-1994	Baeder et al			
	J	US-5,206,018	04-27-1993	Sehgal et al			
	K	US-5,286,730	02-15-1994	Caufield et al			
	L	US-5,286,731	02-15-1994	Caufield et al			
	M	US-5,288,711	02-22-1994	Mitchell et al			
	N	US-5,387,589	02-07-1995	Prasad S. Kulkarni			
	O	US-5,496,832	03-05-1996	Jay J. Armstrong			
	P	US-5,516,781	05-14-1996	Morris et al			
	Q	US-5,561,138	10-01-1996	Jay J. Armstrong			
	R	US-5,665,772	09-09-1997	Cottens et al			
	S	US-6,277,983	08-21-01	Shaw et al			
	BF	T	US-5,728,710	03-17-1998	Luengo		
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
BF	U	EP	0525960	A1	03-02-1993	Miller	
BF	V	PCT	WO 02/066019	A2	08-29-2002	Novartis AG	
Examiner Signature: /Brandon Fetterolf/				Date Considered	06/01/2006		

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				Group Art Unit	
				Examiner Name	
Sheet	3	of	6	Attorney Docket Number	AM101323USA

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), coloumeousse number(s), publisher, city and/or country where published	T <sup>2</sup>	
BF	FF	SEHGAL ET AL, Rapamycin (AY-22, 989), A New Antifungal Antibiotic, II. Fermentation, Isolation and Characterization, The Journal of Antibiotics, Vol. XXVIII No. 10, pp. 727-732 (October 1975)		
BF	GG	CALNE ET AL, Prolonged Survival of Pig Orthotopic Heart Grafts Treated with Cyclosporin A, The Lancet, pp. 1183-1185 (June 3, 1978)		
BF	HH	BAKER ET AL, Rapamycin (AY-22,989), A New Antifungal Antibiotic, III. In Vitro and In Vivo Evaluation, The Journal of Antibiotics, Vol. XXXI, No. 6, pp. 539-545, (June 1978)		
BF	II	MARTEL ET AL, Inhibition of the Immune Response by Rapamycin, a New Antifungal Antibiotic, Can. J. Physiol. Pharmacol. Vol.55, pp. 48-51 (1977)		
BF	FF	VEZINA ET AL, Rapamycin (AY-22,989) A new Antifungal Antibiotic, I. Taxonomy of the Producing Streptomycete and Isolation of the Active Principle, The Journal of Antibiotics, pp. 721-726 (October 1975)		
BF	GG	DUMONT ET AL, Rapamycin Blocks the Immunosuppressive Effect of FK506 But Not That of Cyclosporin A, FASEB JOURNAL, 5256, Vol. 3, No. 4, (1989)		
BF	HH	STARUCH ET AL, FK506 and Rapamycin Inhibit Murine T Cell Activation Through Different Mechanisms, The FASEB Journal, Vol. 3, No. 3, 3411, (1989)		
BF	II	J. ALEXANDRE et al, Rapamycin and CCI-779, Bull. Cancer, 86 (10):808-11, XP-001078856 (October 1999)		
BF	JJ	A. PERREN ET AL, Immunohistochemical Evidence of Loss of PTEN Expression in Primary Ductal Adenocarcinomas the Breast, AM. J. Pathology, 155, (4):1253-60, (October 1999)		
BF	KK	J.E. DANCEY ET AL, Rapamycin-Sensitive Signal-Transduction Pathways: Protein Translation Control of Cell Proliferation, ASCO Educational Book, pp. 68-75, Spring 2000		
BF	LL	M. HIDALGO ET AL, The Rapamycin-Sensitive Signal Transduction Pathway as a Target for Cancer Therapy, Oncogene, 19, pp. 6680-6686, (December 27, 2000)		
BF	MM	E.A. SAUSVILE ET AL, New Agents-Noncytotoxins, Antiangiogenesis, VON-Genetics Institute, ASCO Educational Book, Fall 1998, pp. 112-117		

Examiner Signature	/Brandon Fetterolf/	Date Considered	06/01/2006
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BF	NN	T. SCHMELZLE ET AL, TOR, a Central Controller of Cell Growth, Cell, vol.103, pp. 253-262, (October 13, 2000)		
BF	OO	J. ALEXANDRE ET AL, CCI-779, A New Rapamycin Analog, has Antitumor Activity at Doses Inducing only Mild Cutaneous Effects and Mucositis; Early Results of an Ongoing Phase 1 Study, Proceedings of the 10 <sup>th</sup> NCI/EORTC/AACR Symposium, (1999) (Poster Presentation)		
BF	PP	J. GIBBONS ET AL, The Effect of CCI-779, A Novel Macrolide Anti-Tumor Agent, on the Growth of Human Tumor Cells In Vitro and In Nude Mouse Xenografts In Vivo, Proceedings of the American Association for cancer Research, 301a, 40, (March 1999)		
BF	QQ	B. GEORGER ET AL, Proceedings of the American Association for Cancer Research, (1999), 603a, 40		
BF	RR	J. ALEXANDRE ET AL, Phase 1 Study of CCI-779 a Novel Rapamycin Analog Preliminary Results, Proceedings of the American Association for Cancer Research, 613, 41, (March 2000)		
BF	SS	M. HIDALGO ET AL, Phase 1 and Pharmacological Study of CCI-779, A Cell Cycle Inhibitor, Clinical Cancer Research, Proceedings of the 11 <sup>th</sup> NCI/EORTC/AACR Symposium, 4548s, 6, (November 2000)		
BF	TT	M. HIDALGO ET AL, A Phase 1 and Pharmacological Study of CCI-779, a Rapamycin Ester Cell Cycle Inhibitor, Annals of Oncology, 133a, 11 (4), (October 2000)		
BF	UU	E. RAYMOND ET AL, CCI-779, an Ester Analog of Rapamycin that Interacts with PTEN/PI3 Kinase Pathways: A Phase Study utilizing a Weekly intravenous Schedule, Clinical Cancer Research, Proceedings of the 11 <sup>th</sup> NCI/EORTC/AACR Symposium, Ab. 414, Vol. 6, (November 2000)		
BF	VV	E. RAYMOND ET AL, CCI-779, A Rapamycin Analog with Antitumor Activity: A phase I Study Utilizing a Weekly Schedule, Proceedings of ASCO, 187a, Vol. 19, (2000)		
BF	WW	M. HIDALGO ET AL, Phase 1 and Pharmacological Studies with the Rapamycin Analog CCI-779 Administered as a 30 Minute Fusion, NCI-CTEP Drug Development Meeting, October 1999		
BF	XX	M. ABOU-GHARBIA ET AL, Medicinal Chemistry Approaches for Optimization of Early Leads in Drug Candidates: The Discovery of Calicheamicin, Rapamycin and EAA-090, International Conference on Pure and Applied Heterocyclic Chemistry, (March 2000)		
BF	YY	R. LANGRETH ET AL, Drug Progress on hard-to-Treat Cancers is Cited, The Wall Street Journal, Vol. 234, (November 17, 1999)		
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BF	ZZ	GEORGER ET AL, Antitumor Acitivity of the Rapamycin Analog CCI-779 in Human Primitive Neuroectodermal Tumor/Medulloblastoma Models as Single Agent and in Combination Chemotherapy, Cancer Research, Vol. 61, No. 4, pp. 1527-1532, (February 15, 2001),		
BF	AAA	SCHWARTSMANN G. ET AL, Marine organisms and other novel Natural Sources of New Cancer Drugs, Annals of Oncology, Vol. 11, No. 3, pp. 235-243, (October 13, 2000)		
BF	BBB	CARTER ET AL, Chemotherapy of Cancer, Second edition, John Wiley & Sons, N.Y. N.Y. (1981), pp. 362-365		
BF	CCC	TSAI ET AL, Combination Cytotoxic Effects of Cis-Diamminedichloroplatinum (II) and 5-Fluorouracil with and without Leucovorin against Human Non-small Cell Lung Cancer Cell Lines, Cancer Res. 53, (5), pp. 1079-84 (1993) Abstract only		
BF	DDD	ENG, C. P. ET AL, Activity of Rapamycin (AY-22,989) Against Transplanted Tumors, The Journal of Antibiotics, Vol. 37, No. 10, pp. 1231-1237, (October 1984)		
BF	EEE	PUNT, C.J. ET AL, A Phase 1 Study of Escalating Doses of CCI-779 in combination with 5-Fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplement 6, pg. S17, (October 2001)		
BF	FFF	BONI, J. ET AL, Pharmacokinetics of Escalting Doses of CCI-779 in Combination with 5-Fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplemental 6, Page S68, (October 2001)		
BF	GGG	GUPTA ET AL, Combinations for Cancer Prevention, Nature Medicine, Vol. 6, No. 9, (September 2000)		
BF	HHH	GREENBERGER ET AL, A New Irreversible Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase for the Treatment of Cancer, Clinical Cancer Research, Vol. 6, pg. 38 (November 2000)		
BF	III	TORRANCE ET AL, Combinatorial Chemoprevention of Intestinal Neoplasia, Nature Medicine, Vol. 6, pg. 8, (September 2000)		
BF	JJJ	SHI ET AL, Rapamycin Enhances Apoptosis and Increases Sensitivity to Cisplatin in Vitro, Cancer Research, 55, pgs. 1982-1988, (May 1, 1995)		
BF	KKK	DORLAND'S Illustrated Medical Dictionary, p. 987, (1965)		

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#### OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS

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BF	LLL	ALBERTS, New Perspectives on an Old Friend: Optimizing Carboplatin for the Treatment of Solid Tumors, Oncologist, 3(1), pp. 15-34, (1998) ABSTRACT	
BF	MMM	CLACKSON ET AL, Broad Anti-tumor Activity of ap23573, an mTOR Inhibitor in Clinical Development, Proc A, Soc Clin Oncol 22:Page 220, (2003) (Abstract 882)	

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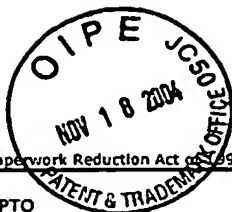
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		Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
BF	NNN	WO-03/103701-A1	12-18-2003	Waratah Pharmaceuticals (Brand, et al.)		
BF	OOO	WO-2004/026280-A2	04-01-2004	Wyeth (Ashraf, et al.)		

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